HPV test and post-treatment and long term follow up

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In women treated for a high-grade premalignant cervical lesion (CIN 2/3) the overall prevalence for recurrent disease is stated between 5 and 30 percent, with the majority occurring in the first two years after initial treatment. However, even after...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29304

Bron
NTR

Verkorte titel
N/A

Aandoening

Cervical Intraepithelial neoplasia (CIN), Human Papillomavirus (HPV), post-treatment, long term, recurrence, recidive
In Dutch: (pre)maligne afwijkingen cervix,
CIN, Humaan papillomavirus (HPV), post-treatment, lange termijn, recidief

Ondersteuning

Primaire sponsor: HUMAVAC (VU University Medical Center)
Overige ondersteuning: HUMAVAC (VU University Medical Center)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of histological confirmed cases of high-grade disease (including CIN 2/3, AIS and VaIN 2/3), diagnosed after a follow up period of up to 18 years after treatment.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

In the Netherlands, each year over 5000 women are treated for a high-grade premalignant cervical lesion (Cervical Intraepithelial Neoplasia – CIN). Since a persistent infection with the human papillomavirus (HPV) is the key causative agent in the carcinogenesis, the presence of this virus can be demonstrated by a HPV test (GP5+/6+ PCR enzyme immuno assay). Despite treatment, the overall prevalence for recurrent disease is stated between 5 and 30 percent, with the majority occurring in the first two years after initial treatment. Even after 20 years however, the risk to develop a recurrent lesion is still significantly increased. Furthermore, women who have been treated for prior cervical cancer have a high relative, although low absolute, risk of being diagnosed with anal and/ or vaginal cancer.

If the hrHPV is cleared after treatment, this has a negative predictive value of almost 100 percent. However, hrHPV persistence is highly associated with the recurrence of a premalignant lesion within two years. Only few studies have investigated the predictive value of the hrHPV test on the development of premalignant genital lesions on the long term. More insight into this relation may lead to more efficient strategies to identify the women at risk for recurrent high-grade (cervical) disease.

Objectives:
The primary objective is to determine the positive and negative predictive value of an hrHPV test after treatment for the development of recurrent (cervical) disease on the long term.

The secondary objectives are:

- Determining the most optimal interval between treatment and hrHPV testing in order to predict the recurrence of (cervical) disease.

- To determine the re-occurrence and/or persistence of hrHPV in the study group.

- To determine whether the HPV type-specificity identified in the recurrent disease is linked to the HPV type found in the primary disease.

- To compare the predictive value of an hrHPV test to the predictive value of cytology.

Study design:
The study is designed as a retrospective longitudinal clinical cohort study.

Study population:
The study population is combined out of three previously described cohorts, which all contain women who have been treated by cold-knife cone biopsy or colposcopic guided LLETZ for a high-grade cervical lesion (CIN 2/3) between 1990 and 2004. None of the women had a previous history of cervical pathology. At several intervals post-treatment all women were prospectively monitored by hrHPV sampling and cytology. All cohorts have been tested at intervals of 6, 12 and 24 months post-treatment.

Main study parameters:
The main study parameter is the number of histological confirmed cases of high-grade disease (including CIN 2/3, AIS and VaIN 2/3), diagnosed after a follow-up period of up to 18 years after treatment. The secondary study parameters include the results of hrHPV presence and typing, cervical cytology, the questionnaire (including sexual behavior, smoking and previous vaccination), and the histological results of all endocervical samples and biopsies taken.
Burden and risks associated with participation: Risks and burden are linked to protocol procedures, such as cervical sampling and, if applicable, colposcopy. Although these are routine procedures, carried out by medical qualified personnel, they may cause side effects or discomfort to the subject. However, it is expected that these procedures will generally be well tolerated.

Doel van het onderzoek

In women treated for a high-grade premalignant cervical lesion (CIN 2/3) the overall prevalence for recurrent disease is stated between 5 and 30 percent, with the majority occurring in the first two years after initial treatment. However, even after 20 years, the risk to develop a recurrent lesion is still significantly increased.
hrHPV persistence is highly associated with the recurrence of a premalignant lesion within two years. Only few studies have investigated the predictive value of the hrHPV test on the development of premalignant genital lesions on the long term. More insight into this relation may lead to more efficient strategies to identify the women at risk for recurrent high-grade (cervical) disease.

Onderzoeksopzet

All outcomes will be obtained in the first study visit. Only in case of a positive HPV type and/or a abnormal cervical smear a colposcopy will take place and will histology results of endocervix and biopsies be known in a second visit.

Onderzoeksproduct en/of interventie

1. Cervical/vaginal sample for cytology as well as hrHPV testing.

2. Gynaecological history and questionnaire to identify risk factors.

3. Colposcopy examination at indication.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All subjects must satisfy the following criteria at study entry:

1. Previous participation in one of the following studies: “Addition of high-risk HPV testing improves the current guidelines on follow-up after treatment for Cervical Intraepithelial Neoplasia”, conducted by Nobbenhuis et al., “Condom use promotes regression of cervical intraepithelial neoplasia and clearance of human papillomavirus: a randomized clinical trial” conducted by Hogewoning et al., or “Post treatment CIN: Randomized Clinical Trial using hrHPV testing for prediction of residual/ recurrent disease ”, conducted by Bais et al.

2. Written informed consent prior to enrolment.

3. Sufficient knowledge of the Dutch or English language.

4. The intention to comply with the requirements of the protocol.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2008
Aantal proefpersonen:	440
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1408
NTR-old	NTR1468
Ander register	: CCA/V-ICI 08/61
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A